NOV 9 2000

510(k) Notification:
Replace™ TPS Coated Implant

K002475

Section 6

510(k) Summary

Manufacturer Information:

Submitter's Name:	Nobel Biocare USA, Inc.
Address:	22895 Eastpark Drive Yorba Linda, CA 92887 U.S.A.
Contact's Name:	Don Kennard VP, Research and Development
Phone:	714 282-5071
Date Prepared:	August 2000

Device Names:

Common Name:	Implant
Trade Name:	Replace™ TPS Coated Implants
Classification Name:	Endosseous Implant

Predicate Devices:

The Nobel Biocare Replace™ TPS Coated Implants are substantially equivalent to the following devices:

- Nobelpharma's 3.75mm Implant
- Altiva Immediate Function Dental Implant

Device Description:

The Nobel Biocare Replace ™ TPS Coated Implants are designed to serve as support for prosthetic devices to restore patient chewing function. The implants are 3.5, 4.3, 5.0, and 6.0mm in diameter, and 10, 13, and 16mm lengths which are composed of a titanium body and titanium plasma spray (CP1) coating. They are tapered, have a hexed superior surface, and are threaded.

Intended Use:

To replace missing tooth roots for single tooth, partial tooth, and fully edentulous patients.

The Nobel Biocare Replace™ TPS Coated Implants system is designed to become osseointegrated prosthesis allowing the attachment of a partial or a complete prosthodontic appliance. The Nobel Biocare Replace™ TPS Coated Implants is designed to be placed in immediate function with a temporary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 9 2000

Mr. Don Kennard
Vice President of Research and Development
Nobel Biocare USA, Incorporated
22895 Eastpark Drive
Yorba Linda, California 92887

Re: K002475
Trade Name: Replace TPS Coated Implants
Regulatory Class: III
Product Code: DZE
Dated: August 7, 2000
Received: August 11, 2000

Dear Mr. Kennard:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

this letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 9

Indications for Use

510(k) Number (if known): K002475

Device Name: Replace™ TPS Coated Implants

Indications for Use:

To replace missing tooth roots for single tooth, partial tooth, and fully edentulous patients.

The Nobel Biocare Replace™ TPS Coated Implants system is designed to become an osseointegrated prosthesis allowing the attachment of a partial or a complete prosthodontic appliance. The Nobel Biocare Replace™ TPS Coated Implants is designed to be placed in immediate function with a temporary recognizing sufficient bone stability (type I or II bone) and appropriate occlusal loading..

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Runy

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002475